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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,493	10/27/2000	Billy G. Anderson	LN.013C4	3853

7590 06/17/2002

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EXAMINER

PRIDDY, MICHAEL B

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/698,493

Applicant(s)
Anderson et al.

Examiner
Priddy, Michael

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3732



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 3, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-139 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on Apr 3, 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 04/03/2002 have been approved by the examiner. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Objections

Claim 130 is objected to because of the following informalities: in line 2, "traverses" should be --traverse--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 124 and 135 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 124 requires textured top and bottom surfaces to be disposed parallel to interfaces of said bone portions. The claim also requires the composite bone graft be shaped as a cervical wedge having an anterior height different from its posterior height.

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It is unclear how the top and bottom surfaces may both be parallel to the interfaces of said bone portions if the surfaces cannot be parallel to each other (as inherent from the wedge shape).

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.d. 887, 225 USPO 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.d. 937, 214 USPO 761 (CCA 1982); *In re Voges*, 422 F.d. 438, 164 USPO 619 (CCA 1970); and, *In re Thorington*, 418 F.d. 528, 163 USPO 644 (CCA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 110-139 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,200,347. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming what is essentially the same invention only in some cases in slightly different and/or broader language.

Terminal Disclaimer

The terminal disclaimer filed 04/03/2002 does not comply with 37 CFR 1.321(b) and/or (c) because:

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The disclaimer fee of \$55.00 in accordance with 37 CFR 1.20(d) has not been submitted, nor is there any authorization in the application file to charge a specified Deposit Account or credit card.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 117-119 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyce et al.(6,123,731). Boyce et al. teach a bone-derived implant 20 comprised of alternating layers 22 and 23 of cortical bone demineralized to different degrees. The sources of the bone are preferably allogenic but may also include xenogenic sources. The alternating layers are bound together mechanically and/or with chemical linking. Mechanical engaging features include tongue-and-groove, mortise-and-tenon or mechanical fasteners such as pins, screws or dowels fabricated from natural or synthetic materials. Boyce et al. also teaches that one or more pharmaceutically active agents may be incorporated into the bone-derived implant. These agents, as listed in columns 4 and 5, may include antibiotics and/or growth factors. Finally, Fig. 3 shows the bone-derived implant 20 installed in the vertebral column of a patient.

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The limitation requiring the pins to be perpendicular to an interface of the cortical bone portions, is considered to inherently be within the scope of the invention of Boyce et al. Since Boyce et al. suggest the use of pins to mechanically fasten adjacent layers of the graft, without indicating a specific angle, all angles from parallel to perpendicular are inherently included.

Tongue-and-groove engaging features is believed to be representative of an interlocking projection/depression.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 120/117-119, 133/117, 134/133/117, 136/120/117-119 and 139/134/133/117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. as applied to claims 117-119 above, and further in view of Gresser et al. (6,241,771). Boyce et al. teach all of the limitations of the present invention except particular dimensions and shapes recited, that the top and bottom surfaces include a plurality of continuous linear protrusions defining a saw-tooth pattern and that the graft includes a through-hole which entirely traverses the graft.

Gresser et al. teach a resorbable interbody spinal fusion device having a top face 11, a bottom face 12, side faces 13, a front end 14 and a back end 15. Top and bottom surfaces 11 and

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12 include a plurality of serrations 16 to aid in anchoring the device to surrounding bone.

Furthermore, the device includes through holes 18 for the introduction of autologous bone.

It would have been obvious to one of skill in the art at the time of the present invention to have formed teeth on the top and bottom surfaces of the graft of Boyce et al. so as to improve its anchorage into surrounding bone. It would also have been obvious to one of skill in the art at the time of the present invention to have provided through-holes in the Boyce et al. invention to allow for bone ingrowth.

Boyce et al. teach that the height dimension of the parallel block 20 is from about 2 to 20 mm. This places the block in the same size range as the present invention. Boyce et al. teach that different shapes may be used for different applications as exemplified by lines 32-38 of column 5. The exact dimensions and shape of the block, including chamfered edges, would have been an obvious matter of design to one of skill in the art at the time of the present invention and dependent upon the intended application.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Thurs. from 7:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Mr. Nicholas Lucchesi, can be reached on (703) 308-2698.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy
Michael B. Priddy
06/10/2002

Nicholas D. Lucchesi
NICHOLAS D. LUCCHESI
PRIMARY EXAMINER
GROUP 3300